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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,983	11/28/2000	Scott A. Waldman	TJU-2444	8378

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EXAMINER

NICKOL, GARY B

ART UNIT	PAPER NUMBER
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1642

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DATE MAILED: 01/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,983

Applicant(s)

WALDMAN, SCOTT A.

Examiner

Gary B. Nickol Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23, 28-30, 36 and 50-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23, 28-30, 36, and 50-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Response to Amendment

The Amendment filed June 30, 2003 (Paper No. 10) in response to the Office Action of December 31, 2002 is acknowledged and has been entered.

Claims 1-22, 24-27, 31-35, and 37-49 are cancelled.

Claims 50-57 were added.

Claims 23, 28-30, 36, and 50-57 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Election/Restrictions

Applicants correctly argue (Paper No. 10, page 11) that claim 29 should not have been withdrawn from consideration. Claim 29 is hereby re-instated into the examination.

New Rejections/Objections:

Claim 29 is objected to under 37 CFR 1.75(c), as being of improper dependent form as it appears that Claim 29 does not further limit the subject matter of Claim 23. Claim 23 recites that the active agent "causes cell death" whereas Claim 29 recites that the active agent is a "cytotoxic agent". Since an agent that is cytotoxic causes cell death, it is not clear how Claim 29 further

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limits the scope of the claimed subject matter in Claim 23. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 23, 28-30, 36, and 50-57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons of record in Paper No. 9, pages 3-6.

Applicants argue (Paper No. 10, page 12) that the reasoning and evidence of record is insufficient to provide sufficient doubt of the truthfulness of Applicant's assertion of enablement and that the evidence of record supports the conclusion that one skilled in the art would accept the truth of Applicant's assertion of enablement. This argument has been considered but is not found persuasive. Applicants fail to disclose how the reasoning and evidence of record clearly enables methods of treating metastatic colorectal cancer via antibody-based therapies in view of the unpredictability of the prior art. For example, applicants argue that the claims have been amended to refer to methods of treating an individual suspected of suffering from metastatic colorectal cancer wherein applicants point out that the ST receptors, which are being targeted, are not normally expressed outside of the intestine/colon. Thus, applicants argue that the compositions may be administered such that they will not interact with normal colon tissue that expresses the receptor, but will bind with cells outside the intestinal tract, such as metastasized colorectal cells. However, applicant's amendment and response fails to discuss how the *claimed* invention overcomes or does not parallel the totality of inherent difficulties one of skill in the art

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would face with administering the claimed antibodies. As set forth previously, these burdens include impaired distribution and delivery of antibody to the tumor site, inadequate trafficking of potential cellular effectors to tumor, antigenic heterogeneity, shed or internalized targets, insufficient target specificity, and induction of HAMA. Thus, in view of the lack of predictability, the nature of the invention, and the lack of working examples, applicant's arguments are not found persuasive and the rejection is maintained.

Claims 23, 28-30, 36, and 50-57 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 9-10, 30-31, 55-56, 58 of U.S. Patent No. 5,879,656 ('656). The patented claims, broadly drawn to a method of treating an individual suspected of suffering from metastasized colorectal cancer comprising administering a "conjugated" compound comprising an ST binding moiety and an active moiety, represents an obvious variation or species of the pending claims drawn to treating an individual suspected of suffering from metastatic colorectal cancer comprising administering an ST receptor ligand and an active agent (see previous rejection in Paper No. 9, pages 7-8). Applicants have only "proposed" to file a Terminal Disclaimer (Paper No. 10, page 14), and the thus the rejection is maintained.

All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
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GBN
January 2, 2004

